UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL NO. 16-2738 (FLW) (LGH)**

This document relates to:
***James Chakalos, as personal representative on behalf of the Estate of Janice Chakalos v. Johnson & Johnson et al.*, Case. No. 3:14-cv-7079**

PLAINTIFFS' STATUS REPORT

Pursuant to this Court's directive, Counsel submits the following Status Report in order to better inform the Court of the status of the litigation.

I. General Factual Background of the Cases

Johnson and Johnson's Baby Powder was introduced to the market in 1893. Since that time, Johnson & Johnson and its subsidiaries have marketed Baby Powder as a safe, mild product intended for use by both mothers and babies. Johnson's Baby Powder is composed, almost exclusively, of pure talc, a soft mineral comprised of magnesium, silicon, oxygen, and hydrogen. In 1966, Johnson & Johnson developed Shower to Shower, another talc-based body powder. Each of these products is marketed for feminine hygiene use, including perineal (genital) application, to limit perspiration, chafing, and other discomfort. Imerys Talc America, Inc. provides all of the talc used in Johnson & Johnson's talc-based body powders.

In 1971, the first study to indicate a possible association between the perineal application of talcum powder and ovarian cancer was conducted by W.J. Henderson in Cardiff, Wales.[1] In

[1] W.J. Henderson, et al. *Talc and Carcinoma of the Ovary and Cervix*, 78 J. Obst. Gyn. Brit. Common. 266 (March 1971).

1982, Dr. Daniel Cramer conducted the first case-control study of perineal talcum powder use and ovarian cancer and found a significant increased risk of ovarian cancer among women who use talcum powders in the genital area.[2] Since 1982, numerous studies (27+ studies through October 2016)[3], involving many of the most esteemed epidemiologists in the world, have consistently

[2] Cramer et al., *Ovarian Cancer and Talc: A Case-Control Study*, 50 Cancer 372 (1982).

[3] Henderson, W.J., Joslin, C.A.F., Turnbull, A.C., and Griffiths, K. "Talc and Carcinoma of the Ovary and Cervix." The Journal of Obsetrics and Gynaecology of the British Commonwealth, March, 1971. Vol. 78. pp. 266-272; Cramer, D. W., W. R. Welch, R. E. Scully, and C. A. Wojciechowski. "Ovarian Cancer and Talc: A Case-Control Study." Cancer 50, no. 2 (July 15, 1982): 372–76.; Hartge, P., R. Hoover, L. P. Lesher, and L. McGowan. "Talc and Ovarian Cancer." JAMA: The Journal of the American Medical Association 250, no. 14 (October 14, 1983): 1844.; Whittemore, A. S., M. L. Wu, R. S. Paffenbarger, D. L. Sarles, J. B. Kampert, S. Grosser, D. L. Jung, S. Ballon, and M. Hendrickson. "Personal and Environmental Characteristics Related to Epithelial Ovarian Cancer. II. Exposures to Talcum Powder, Tobacco, Alcohol, and Coffee." American Journal of Epidemiology 128, no. 6 (December 1988): 1228–40.; Harlow, B. L., and N. S. Weiss. "A Case-Control Study of Borderline Ovarian Tumors: The Influence of Perineal Exposure to Talc." American Journal of Epidemiology 130, no. 2 (August 1989): 390–94.; Harlow, B. L., D. W. Cramer, D. A. Bell, and W. R. Welch. "Perineal Exposure to Talc and Ovarian Cancer Risk." Obstetrics and Gynecology 80, no. 1 (July 1992): 19–26.; Tzonou, A., A. Polychronopoulou, C. C. Hsieh, A. Rebelakos, A. Karakatsani, and D. Trichopoulos. "Hair Dyes, Analgesics, Tranquilizers and Perineal Talc Application as Risk Factors for Ovarian Cancer." International Journal of Cancer. Journal International Du Cancer 55, no. 3 (September 30, 1993): 408–10.; Chang, S., and H. A. Risch. "Perineal Talc Exposure and Risk of Ovarian Carcinoma." Cancer 79, no. 12 (June 15, 1997): 2396–2401.; Cook, Linda S., Mary L. Kamb, and Noel S. Weiss. "Perineal Powder Exposure and the Risk of Ovarian Cancer." American Journal of Epidemiology 145, no. 5 (March 1, 1997): 459–65.; Cramer, D. W., R. F. Liberman, L. Titus-Ernstoff, W. R. Welch, E. R. Greenberg, J. A. Baron, and B. L. Harlow. "Genital Talc Exposure and Risk of Ovarian Cancer." International Journal of Cancer. Journal International Du Cancer 81, no. 3 (May 5, 1999): 351–56.; Wong, C., R. E. Hempling, M. S. Piver, N. Natarajan, and C. J. Mettlin. "Perineal Talc Exposure and Subsequent Epithelial Ovarian Cancer: A Case-Control Study." Obstetrics and Gynecology 93, no. 3 (March 1999): 372–76.; Gertig, D. M., D. J. Hunter, D. W. Cramer, G. A. Colditz, F. E. Speizer, W. C. Willett, and S. E. Hankinson. "Prospective Study of Talc Use and Ovarian Cancer." Journal of the National Cancer Institute 92, no. 3 (February 2, 2000): 249–52.; Mills, Paul K., Deborah G. Riordan, Rosemary D. Cress, and Heather A. Young. "Perineal Talc Exposure and Epithelial Ovarian Cancer Risk in the Central Valley of California." International Journal of Cancer. Journal International Du Cancer 112, no. 3 (November 10, 2004): 458–64. doi:10.1002/ijc.20434.; Gates, Margaret A., Shelley S. Tworoger, Kathryn L. Terry, Linda Titus-Ernstoff, Bernard Rosner, Immaculata De Vivo, Daniel W. Cramer, and Susan E. Hankinson. "Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer." Cancer Epidemiology, Biomarkers & Prevention: A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology 17, no. 9 (September 2008): 2436–44. doi:10.1158/1055-9965.EPI-08-0399.; Wu, Anna H., Pearce, Celeste L., Tseng, Chiu-Chen, Templeman, Claire, and Pike, Malcolm C. "Markers of inflammation and Risk of ovarian cancer in Los Angeles County."; Rosenblatt, Karin A., Noel S. Weiss, Kara L. Cushing-Haugen, Kristine G. Wicklund, and Mary Anne Rossing. "Genital Powder Exposure and the Risk of Epithelial Ovarian Cancer." Cancer Causes & Control: CCC 22, no. 5 (May 2011): 737–42. doi:10.1007/s10552-011-9746-3.; Houghton, Serena C., Katherine W. Reeves, Susan E. Hankinson, Lori Crawford, Dorothy Lane, Jean Wactawski-Wende, Cynthia A. Thomson, Judith K. Ockene, and Susan R. Sturgeon. "Perineal Powder Use and Risk of Ovarian Cancer." Journal of the National Cancer Institute 106, no. 9 (September 2014). doi:10.1093/jnci/dju208.; Cramer, Daniel W., Allison F. Vitonis, Kathryn L. Terry, William R. Welch, and Linda J. Titus. "The Association between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States." Epidemiology (Cambridge, Mass.), December 17, 2015. doi:10.1097/EDE.0000000000000434.; Schildkraut, Joellen M., et al. "Association Between Body Powder Use and Ovarian Cancer: the African American Cancer Epidemiology Study (AACES). Published Online with the American Association for Cancer Research, May 12, 2016; Gonzalez, Nicole L., et al. "Douching, Talc Use, and Risk of Ovarian Cancer." Epidemiology Publish Ahead of Print, June 20, 2016.

shown an increased risk of ovarian cancer associated with perineal talc use. Out of these 27 studies, all but one of them found a statistically significant increased risk of ovarian cancer from talc use.

Beginning in September 1971, Johnson & Johnson developed a strategy to refute or discredit the Henderson findings. This included criticizing the Henderson study's techniques, validity, tissues, and references. Johnson & Johnson also focused on trying to prove the purity of the talc they used in their products, rather than performing research to determine if talc itself had any adverse effects when embedded in ovarian tissues. This effort continued for the next 10 years and only intensified after the 1982 study performed by Dr. Cramer. Numerous Johnson & Johnson and Imerys internal documents acknowledge the increasing health concerns involved with genital talc use and ovarian cancer.

In 2005, the International Agency for the Research on Cancer (IARC), an organization that is part of the World Health Organization, voted in favor of declaring perineal use of cosmetic grade talc a group 2B carcinogen, i.e., "possibly carcinogenic to human beings." IARC's rationale for this ruling was: "For perineal use of talc-based body powder, many case–control studies of ovarian cancer found a modest, but unusually consistent, excess in risk, although the impact of bias and potential confounding could not be ruled out." Since IARC pronouncement, Imerys has placed a warning on the talc Material Safety Data Sheets (MSDS) that it sends to Johnson & Johnson, acknowledging that genital talc use may increase the risk of ovarian cancer.

Internal documents from Johnson & Johnson and Imerys Talc America demonstrate that, despite their knowledge of the risk of harm to women, these companies, along with their trade association, the Personal Care Products Council ("PCPC"), actively concealed information regarding the dangers of genital talcum powder use from consumers. Both companies have

actively attempted to influence regulatory agencies in an effort to prevent governmental regulation of talc use. This has included the formation of the Talc Interested Party Task Force, formed under the auspices of the Cosmetic Toiletry and Fragrancy Association, for the purpose of defending talc-based products. Over the years this task force and other industry-sponsored groups have worked to influence the NTP, FDA, NIH, NIEHS, and other regulatory agencies.

Despite consistent evidence of a causal connection between perineal application of talcum powder and ovarian cancer, neither Johnson's Baby Powder nor Shower to Shower have been removed from the market or altered to remove talc as a main ingredient. Johnson & Johnson continues to sell these talc-based body powders without a consumer warning.

As a direct result of the Defendants' actions, untold numbers of women continue to use these products on a daily basis, and thousands of women have been diagnosed with cancer. Over the past few decades, this has led to countless avoidable deaths from ovarian cancer caused by the genital use of talcum powder.

II. Discovery in *Chakalos, et al. v. Johnson & Johnson et al.,*

When this case was filed it was a single plaintiff and both sides were cognizant of the new discovery rules regarding proportionality. Many of the discovery decisions were made based on our single case and should not be extended to the entire MDL. Now that this case is part of an MDL, it would be prejudicial to the Plaintiff to prevent him from benefiting from the coordination of discovery and from the additional discovery that will likely become available to other plaintiffs.

Initial fact discovery is completed. Plaintiff has answered individual interrogatories and requests to produce. Six case specific depositions have taken place including the Plaintiff (Mr. Chakalos), Ms. Chakalos' sister, Ms. Chakalos' son and three of her physicians.

Defendants have produced the documents that were produced in *Berg v. Johnson & Johnson, et al*. (D.S.D. 2013) and the St. Louis litigation. Privilege logs have also been produced.

No corporate depositions have been taken in this case but the parties agreed to use the corporate depositions that were taken in *Berg v. Johnson & Johnson, et al*. (D.S.D. 2013).

The parties initially named experts. The Defendants named numerous, and some duplicative, experts that Counsel believes have been used in other venues. After the initial failing, the remaining expert discovery deadlines were stayed pending issues with potentially destructive testing and obtaining the tissue samples from Memorial Sloan Kettering Cancer Center. Magistrate Goodman had telephone conversations with the parties and entered an order regarding the pathology samples. Plaintiff filed a motion to compel the production of the materials requested in their subpoena in the S.D.N.Y. and recently obtained the tissue from the hospital which has been sent to a new expert for analysis.

III. Settlement

Magistrate Goodman suggested a settlement conference and it was originally included on the scheduling order. However, Defendants indicated that the discussions would not be productive until after expert report disclosures so the conference was cancelled pending the production of reports. There have been no further discussions.

IV. Pending Motions

There are no pending motions before this Court, either related to the MDL or motions that were pending prior to the formation of the MDL. The related Motion to Compel in the S.D.N.Y. was granted regarding production of tissue from Memorial Sloan Kettering Cancer Center.

V. Proposed Lead and Liaison Counsel

Counsel for all Plaintiffs with cases pending before this Court have met and conferred. There is unanimous agreement that Michelle A. Parfitt and P. Leigh O'Dell serve as Co-Lead Counsel of the MDL. Counsel propose that Christopher M. Placitella be appointed as Liaison Counsel.

Ms. Parfitt and Ms. O'Dell will represent the interests of Plaintiffs who have alleged personal injury claims during the Organizational Conference.

VI. Proposed Agenda Items

Counsel for Plaintiffs propose the following agenda items that may be discussed during the Organizational Conference:

A. Appointment of the Plaintiffs Steering Committee;
   i. Appointment of Committee Chairs and Members;
   ii. State/Federal Liaison

B. Service of Papers.
   i. Generate Corrected Service List;
   ii. Potential for Use of a Counsel Contact Information Form;
   iii. Potential for Stipulation Related to Waiver and Electronic Service Defendants

C. Direct Filing Order

D. Master Complaint/Short Form Complaints

E. Master Answer/Short Form Answers

F. Protective Order

G. ESI Protocol

H. Document Production Protocols

I. Preservation/Extremis Depositions

J. Tissue Preservation Protocol

K. Plaintiff Fact Sheets/Defendant Fact Sheets

L. Role of Magistrate Judge

Dated: November 10, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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